

July 24, 2009

Dear Medical Use Licensee:

The Illinois Emergency Management Agency (the Agency) hereby issues an exemption pursuant to 32 Ill. Adm. Code 310.30(a) from certain provisions in 32 Ill. Adm. Code 330 and 335 to all Illinois medical use licensees during times of molybdenum-99 shortages in the United States. The intent of this Exemption is to assure that during times of limited supply the available technetium-99m is used for patient administrations.

Because of the unexpected shutdown of a major Canadian supplier, the supply chain for fission-produced medical isotopes may shrink dramatically from time to time. Therefore, this Exemption may be needed intermittently until the supply of molybdenum-99 permanently stabilizes. The Exemption must be maintained with the license and discussed with the licensee's radiation safety officer and authorized users. The Exemption can only provide relief from the regulations; it does not provide relief from specific license conditions. You may contact the Radioactive Materials Section if you believe that there are license conditions that also affect the availability of technetium-99m for patient treatments.

The Exemption addresses the following requirements:

1. Notwithstanding the requirements in 32. Ill Adm. Code 335.2010(b) to calibrate the instrumentation required in paragraph (a) of this section in accordance with nationally recognized standards, the licensee is not required to perform the calibration test at the maximum activity of administered doses or at the time interval specified in the national standard if: (i) the licensee would use technetium-99m that is needed to administer to a patient to perform the test; (ii) the licensee certifies in writing that the quantities of technetium-99m that it is receiving from its supplier is less than what the licensee has ordered or procured and is not sufficient to perform the test in accordance with the national standard; and (iii) the licensee's supplier provides written documentation, that the supplier is providing reduced quantities of technetium-99m to the licensee as a result of production shortages of molybdenum-99 affecting its generator or technetium-99m. **[NOTE: IF THERE IS A CALIBRATION LICENSE CONDITION, THE LICENSEE NEEDS TO TAKE AN ACTION TO AMEND THE CONDITION TO ALLOW THE CHANGE IN CALIBRATION; THE EXEMPTION BY ITSELF WILL NOT ALLOW THE LICENSEE TO ACCOMPLISH THESE ACTIONS.]** The licensee must perform the calibration test as soon as adequate supplies become available, and document results of the test in accordance with Section 335.2010. If adequate supplies become available, the licensee cannot defer performing the tests until the next time interval. The licensee shall maintain records of its certification and the underlying documentation supporting the licensee's certification, and the supplier's written documentation for 5 years.



2. Notwithstanding the requirements in 32. Ill Adm. Code 335.3010(a) and 35.4010(a) to obtain unsealed radioactive material prepared for medical use for uptake, dilution, excretion, imaging or localization studies from a manufacturer or preparer licensed under 32. Ill Adm. Code 330.260(c), the licensee may obtain technetium-99m, or dosages of technetium-99m radioactive drugs, from another Illinois, Agreement State or Nuclear Regulatory Commission (NRC)-licensed medical use licensee to administer to patients when the licensee is unable to obtain technetium-99m (or unit dosage of a technetium-99m radioactive drug) from its normal supplier as a result of production shortages of molybdenum-99 affecting its generator or technetium-99m supplier, as documented in writing by the supplier. The licensee shall certify in writing that it is receiving reduced quantities of technetium-99m from its supplier and did not have enough to provide the administration(s). The licensee shall maintain a record of the transfer, its certification and the underlying documentation supporting the licensee's certification, and the supplier's certification for 5 years.
3. Notwithstanding the requirements in 32. Ill Adm. Code 330.260(c), the licensee may transfer bulk surplus technetium-99m, or unit dosages of technetium-99m radioactive drugs, to other medical use licensees licensed by Illinois, an Agreement State or the NRC, for administration to patients, but only after the licensee obtains from the receiving medical use licensee a written certification that it is unable to obtain a generator, or bulk technetium-99m or unit dosages of a technetium-99m radioactive drug from its normal supplier as a result of production shortages of molybdenum-99 affecting its generator or technetium-99m supplier. The licensee shall maintain a record of the transfer and the receiving licensee's certification for 5 years.
4. Nothing in this exemption relieves the licensee from complying with the requirements in 32. Ill. Adm. Code 330.260(c)(8).
5. This exemption is effective upon issuance and during periods of United States shortages of molybdenum-99 and technetium-99m as documented in writing by the suppliers of molybdenum-99/technetium-99m generators and technetium-99m radioactive drugs.
6. This exemption must be maintained with the license and discussed with the licensee's Radiation Safety Officer and Authorized Users.

Each of these exemptions is discussed in further detail in the attached documents from the NRC, including the safety bases for granting the exemption. It is believed that this exemption will not endanger life, property, common defense or security because it does not relieve the licensee from Agency requirements for worker or public dose, handling or securing the radioactive materials or handling or securing radioactive waste.

The Agency is very conscious of the superb level of medical care available in Illinois, and we strive to be responsive to healthcare needs in the state. If you have any further questions, please contact my staff in the Radioactive Materials Section at (217)785-9947. Please visit the nuclear safety section of the Agency's website at www.iema.illinois.gov/iema/dns.asp for the latest information concerning the Division of Nuclear Safety's programs. Our website includes important information such as new and proposed requirements, guidance, events and other pertinent items of interest.

Sincerely,

A handwritten signature in black ink, reading "Joseph G. Klinger". The signature is fluid and cursive, with the first name "Joseph" and last name "Klinger" clearly legible.

Joseph G. Klinger
Assistant Director
Illinois Emergency Management Agency

Attachment